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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/509,994 | YUI ET AL. | |
| | Examiner | Art Unit | |
| | Holly Schnizer | 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE filed 4/29/04.
2. ☒ The allowed claim(s) is/are 86,87 and 89-96.
3. ☒ The drawings filed on 05 April 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Philip Dubois on June 30, 2004.

The application has been amended as follows:

IN THE CLAIMS:

Please cancel Claims 72-85, and 88.

Please amend the following claims:

86. (amended) A method for storing/transporting an aqueous injection preparation of thrombomodulin in a non-frozen or non-freeze dried liquid form, comprising:

preparing an aqueous solution having a pH value in a range from 5 to 7.0, wherein said solution contains soluble thrombomodulin and contains buffer component(s) having a buffering action ~~on~~ in a pH range between 5 and 7.0, wherein said aqueous solution further comprises a surfactant,

aseptically packing said aqueous solution in a container wherein said aqueous solution is kept aseptically in the container while being stored/transported,

packaging said container filled with the aqueous solution for storage/transportation in a sheet or in a carton, and
storing and/or transporting said aqueous injection preparation of thrombomodulin in a non-frozen or non-freeze dried liquid form.

87. (amended) A method for storing/transporting an aqueous injection preparation of thrombomodulin in a non-frozen or non-freeze dried liquid form, comprising:

preparing an aqueous solution having a pH value in a range from 5 to 7.0, wherein said solution contains soluble thrombomodulin and contains buffer component(s) having a buffering action ~~on~~ in a pH range between 5 and 7.0, wherein said aqueous solution further comprises a surfactant,

aseptically packing said aqueous solution in a container wherein said aqueous solution is kept aseptically in the container while being stored/transported and said container filled with the aqueous solution is a prefilled syringe preparation, wherein the aqueous solution is in a syringe vessel sealed aseptically by a cap and a stopper, and

packaging said container filled with the aqueous solution for storage/transportation in a sheet or in a carton, and
storing and/or transporting said aqueous injection preparation of thrombomodulin in a non-frozen or non-freeze dried liquid form.

89. (amended) The method according to claim ~~85~~ 86 wherein the soluble thrombomodulin is selected from the group consisting of ~~that constituted of the amino~~

~~acid sequence composed of the amino acid residue from the 19th site to the 516th site of the sequence listing thrombomodulin comprising the sequence of amino acids 19 to 516 of SEQ ID NO:1, that constituted of an amino acid sequence composed of the amino acid residue from the 19th to the 516th site of the sequence listing thrombomodulin comprising the sequence of amino acids 19 to 516 of SEQ ID NO: 2, that obtained by transfecting a DNA segment coding an amino acid sequence given in the sequence listing SEQ ID NO: 1 to a host cell and that obtained by transfecting DNA segment coding an amino acid sequence given in the sequence listing SEQ ID NO: 2 to a host cell.~~

90. (amended) The method according to claim ~~85~~ 86, wherein the pH of the buffer solution is in the range from 5.5 to 6.5.

96. (amended) The method according to claim ~~85~~ 86, wherein said aqueous solution contains 0.05 to 15 mg/ml of soluble thrombomodulin.

Claims 86, 87, and 89-96 are in condition for allowance.

The following is an examiner's statement of reasons for allowance:

There is no teaching or suggestion in the prior art for a method of storing or transporting a non-frozen, non-freeze dried, aqueous solution of thrombomodulin with the same steps as that of the present claims. Kunihiro et al. teaches a thrombomodulin


solution that has the same components as the thrombomodulin solutions stored and/or transported in the presently claimed method, however, Kunihiro et al. teach that the disclosed solutions should be freeze-dried for storage (Col. 12, lines 35-40). The step in the claims that the solution is packaged for storage/transportation in a sheet or carton, clarifies that the claimed method is to be used for longer term storage/transportation than merely making the thrombomodulin solution and immediately giving it to the patient as is done in Example 1 (Col. 9) of Kunihiro et al.

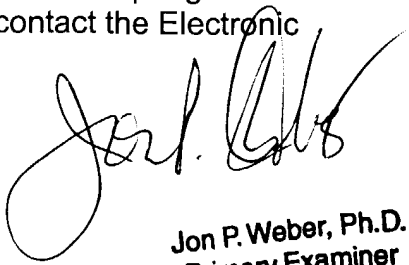
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Holly Schnizer
June 30, 2004


Jon P. Weber, Ph.D.
Primary Examiner